## **CLAIMS**

What is claimed is:

1 1. A method for treating cancer comprising administering to a

2 subject having cancer a sufficient amount of a compound having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer to provide a C<sub>max</sub> of about 20

6 to 4000 ng/mL of the compound in the subject's plasma or a C<sub>max</sub> of about 40

7 to 8000 ng/mL of the compound in the subject's blood.

1 2. The method of claim 1, wherein the amount of the compound is

2 sufficient to provide a C<sub>max</sub> of about 50 to 500 ng/mL of the compound in the

3 subject's plasma or a C<sub>max</sub> of about 100 to 1000 ng/mL of the compound in the

4 subject's blood.

1 3. The method of claim 1, wherein the amount of the compound is

2 sufficient to provide a C<sub>max</sub> of about 50 to 250 ng/mL of the compound in the

3 subject's plasma or a C<sub>max</sub> of about 100 to 500 ng/mL of the compound in the

4 subject's blood.

1 4. The method of claim 1, wherein the amount of the compound is

2 sufficient to provide a C<sub>max</sub> of about 75 to 150 ng/mL of the compound in the

3 subject's plasma or a C<sub>max</sub> of about 150 to 300 ng/mL of the compound in the

4 subject's blood.

1 5. The method of claim 1, wherein the amount of the compound is

2 sufficient to provide a C<sub>max</sub> of about 100 to 2000 ng/mL of the compound in

the subject's plasma or a C<sub>max</sub> of about 200 to 4000 ng/mL of the compound in

4 the subject's blood.

- 1 6. The method of claim 1, wherein the amount of the compound is
- 2 sufficient to provide a C<sub>max</sub> of 100 to 1000 ng/mL of the compound in the
- 3 subject's plasma or a C<sub>max</sub> of about 200 to 2000 ng/mL of the compound in the
- 4 subject's blood.
- 1 7. The method of claim 1, wherein the lactate salt of the compound
- 2 is administered to the subject and the subject is a human.
- 1 8. The method of claim 7, wherein the lactate salt is in an aqueous
- 2 solution and is administered orally to the human subject.
- 1 9. A method for treating cancer comprising administering to a
- 2 subject having cancer a sufficient amount of a compound having the formula:

- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer to provide about 10 to 2,000
- 6 ng/mL of the compound in the subject's plasma 24 hours after administration
- 7 or about 20 to 4,000 ng/mL of the compound in the subject's blood 24 hours
- 8 after administration.
- 1 10. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 20 to 1,000 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 40 to 2,000
- 4 ng/mL of the compound in the subject's blood 24 hours after administration.
- 1 11. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 40 to 500 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 80 to 1,000
- 4 ng/mL of the compound in the subject's blood 24 hours after administration.

- 1 12. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 40 to 250 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 80 to 500 ng/mL
- 4 of the compound in the subject's blood 24 hours after administration.
- 1 13. The method of claim 9, wherein the subject is a human.
- 1 14. The method of claim 13, wherein the lactate salt of the
- 2 compound is administered to the subject.
- 1 15. The method of claim 14, wherein the lactate salt is in a pill,
- 2 capsule, tablet, gelcap, caplet, suspension, or aqueous solution and is
- 3 administered orally to a human subject.
- 1 16. The method of claim 9, wherein the compound is administered
- 2 as a pharmaceutical composition comprising fructose.
- 1 17. The method of claim 16, wherein the pharmaceutical
- 2 composition further comprises a flavoring agent.
- 1 18. The method of claim 17, wherein the flavoring agent comprises
- 2 tetrarome mandarine flavor.
- 1 19. The method of claim 18, wherein the pharmaceutical
- 2 composition further comprises water.
- 1 20. The method of claim 9, further comprising mixing the solid
- 2 compound with water to form an aqueous mixture before administering the
- 3 compound to the subject.
- 1 21. The method of claim 9, wherein the compound is administered
- 2 as a pharmaceutical composition selected from granules, powders,
- 3 suspensions, tablets, pills, capsules, gelcaps, caplets, emulsions, syrups,
- 4 elixirs, slurries, sprays, aerosols, or solutions.

- 1 22. The method of claim 21, wherein the pharmaceutical
- 2 composition is selected from tablets, pills, capsules, gelcaps, or caplets.
- 1 23. The method of claim 9, wherein the compound is administered
- 2 by injection as a short bolus, slow infusion, or long-term infusion.
- 1 24. The method of claim 23, wherein the injection is administered
- 2 once, twice, three times, or four times daily.
- 1 25. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from 0.25 to 30 mg/kg body weight of the
- 3 subject.
- 1 26. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from about 25 to 1500 mg/day.
- 1 27. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from about 200 to 500 mg/day.
- 1 28. The method of claim 9, wherein the cancer to be treated is a
- 2 solid tumor.
- 1 29. The method of claim 9, wherein the cancer to be treated is a
- 2 leukemia.
- 1 30. The method of claim 9, wherein the cancer to be treated is
- 2 selected from prostate, colorectal, breast, multiple myeloma, pancreatic, small
- 3 cell carcinoma, acute myelogenous leukemia, chronic myelogenous leukemia,
- 4 myelo-proliferative disease, nonsmall cell lung, small cell lung, chronic
- 5 lymphoid leukemia, sarcoma, melanoma, lymphoma, thyroid, neuroendocrine,
- 6 renal cell, gastric, gastrointestinal stromal, glioma, brain, or bladder.
- 1 31. The method of claim 9, further comprising administering the
- 2 compound as part of a treatment cycle, wherein the treatment cycle
- 3 comprises administering the amount of the compound daily for 7, 14, 21, or 28
- 4 days, followed by 7 or 14 days without administration of the compound.

- 1 32. The method of claim 31, wherein the treatment cycle comprises
- 2 administering the amount of the compound daily for 7 days, followed by 7
- 3 days without administration of the compound.
- 1 33. The method of claim 31, wherein the treatment cycle is repeated
- 2 one or more times.
- 1 34. The method of claim 31, further comprising administering the
- 2 amount of the compound once, twice, three times, or four times daily during
- 3 the administration phase of the treatment cycle.
- 1 35. The method of claim 9, further comprising administering the
- 2 amount of the compound once, twice, three times, or four times daily or every
- 3 other day during a course of treatment.
- 1 36. A method for treating cancer comprising administering to a
- 2 subject having cancer a sufficient amount of a compound having the formula:

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- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer to provide an AUC of about
- 6 500 to 60,000 ng\*h/mL of the compound in the subject's plasma or about 750
- 7 to 120,000 ng\*h/mL of the compound in the subject's blood.
- 1 37. The method of claim 36, wherein the AUC is about 1,000 to
- 2 30,000 ng\*h/mL of the compound in the subject's plasma or about 1,500 to
- 3 60,000 ng\*h/mL of the compound in the subject's blood.
- 1 38. The method of claim 36, wherein the AUC is about 2,000 to
- 2 15,000 ng\*h/mL of the compound in the subject's plasma or about 3,000 to
- 3 30,000 ng\*h/mL of the compound in the subject's blood.

1 39. A method for determining a metabolic profile for a compound

2 having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer, in a subject, the method

6 comprising measuring the amount of at least one metabolite of the compound

7 in one or more samples of urine, blood, or tissue taken from the subject.

1 40. The method of claim 39, wherein the at least one metabolite is

2 an N-oxide compound having the formula:

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1 41. The method of claim 39, wherein the at least one metabolite is

2 an N-desmethyl compound having the formula:

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1 42. The method of claim 41, wherein the at least one metabolite

2 further includes a second metabolite that is an N-oxide compound having the

3 formula:

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- 1 43. The method of claim 41, wherein the metabolite is measured by
- 2 ultraviolet spectroscopy or liquid chromatography-mass spectroscopy.
- 1 44. A method of determining the amount of a compound having the
- 2 formula:

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- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer in a subject, the method
- 6 comprising measuring the amount of the compound in a sample of urine,
- 7 blood, or tissue taken from the subject after the compound has been
- 8 administered to the subject.
- 1 45. The method of claim 44, further comprising measuring the
- 2 amount of a metabolite of the compound in the sample.
- 1 46. The method of claim 45, wherein the metabolite is an N-oxide
- 2 compound having the formula:

1 47. The method of claim 46, wherein the metabolite is an N-

2 desmethyl compound having the formula:

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1 48. The method of claim 44, further comprising withdrawing two or

2 more samples from the subject at different times after the compound has

3 been administered to the subject.

1 49. A method for treating cancer comprising administering to a

2 subject having cancer a compound having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer, wherein the amount of

6 compound administered to the subject in a first treatment cycle is 25 mg per

7 day, and the amount of compound administered is increased with each

8 subsequent treatment cycle until either 1500 mg of compound is administered

9 to the subject per day or dose-limiting toxicity is observed in the subject.

1 50. The method of claim 49 wherein the amount of compound

administered is doubled with each subsequent treatment cycle after the first.

51. The method of claim 50 wherein the treatment cycle comprises

2 administering the same amount of the compound daily for 7 days followed by

3 7 days without administration of the compound.

- 1 52. A method of treating cancer, comprising administering to a
- 2 subject having cancer, a sufficient amount of a compound having the formula I

- 5 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 6 pharmaceutically acceptable salt of the tautomer, and exposing the subject to
- 7 one or both compounds of formula II and formula III selected from:

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9 II or

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11 III,

- whereby one or both of the compounds of formula II and formula III are
- 13 produced by metabolism of the compound of formula I by the subject, to
- 14 provide a combined  $C_{max}$  for one or more of the compounds of formula I,
- 15 formula II, and formula III ranging from about 20 to about 4000 ng/mL in the
- subject's plasma or a combined C<sub>max</sub> for one or more of the compounds of
- formula I, formula II, and formula III ranging from about 40 to about 8000
- 18 ng/mL in the subject's blood.

- 1 53. A method for treating cancer comprising exposing a subject
- 2 having cancer to an amount of one or more compounds having a formula
- 3 selected from:

F NH<sub>2</sub> N NH N O

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- 7 an active metabolite thereof, a pharmaceutically acceptable salt thereof, a
- 8 tautomer thereof, or a pharmaceutically acceptable salt of the tautomer,
- 9 sufficient to provide a combined C<sub>max</sub> of about 20 to 4000 ng/mL of the one or
- 10 more compounds in the subject's plasma or a combined C<sub>max</sub> of about 40 to
- 11 8000 ng/mL of the one or more compound in the subject's blood.
- 1 54. The method of claim 53, wherein the amount of the one or more
- 2 compounds provides a C<sub>max</sub> for one of the compounds of about 35 to 2600
- 3  $\,$  ng/mL in the subject's plasma or a  $\,$  C<sub>max</sub> for one of the compounds of about 35
- 4 to 6000 ng/mL in the subject's blood.
- 1 55. The method of claim 53, wherein the amount of the one or more
- 2 compounds provides a C<sub>max</sub> for one of the compounds of about 35 to 1200
- 3  $\,$  ng/mL in the subject's plasma or a  $\,$   $\,$   $\,$  C<sub>max</sub> for one of the compounds of about 50
- 4 to 2400 ng/mL in the subject's blood.

1 56. The method of claim 53, wherein the compound of formula:

3 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

4 pharmaceutically acceptable salt of the tautomer is administered to the

5 subject.

6 57. The method of claim 53, wherein the compound of formula:

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8 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

pharmaceutically acceptable salt of the tautomer is administered to the

10 subject.

1 58. The method of claim 53, wherein the compound of formula:

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3 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

4 pharmaceutically acceptable salt of the tautomer is administered to the

5 subject.